Chloroprene

John Vandenberg, PhD
Kris Thayer, PhD
NCEA

October 4, 2018

Background

- Chloroprene is used to manufacture neoprene rubber, used in car door seals, wetsuits, etc.
- **IRIS assessment for chloroprene was completed in 2010 (ORD/NCEA)**
- National Air Toxics Assessment (NATA)(OAR/Office of Air Quality Planning and Standards)
  - EPA released NATA in December 2015, covering emissions year 2011
  - DuPont (now Denka Performance Elastomer) identified as emitting chloroprene (the only chloroprene manufacturing company in the US)
    - Cancer risks ~ 800 in 1,000,000 (**Highest risk facility identified in the 2015 NATA**).
    - New NATA (August 2018) cancer risks ~2,000 in 1,000,000; (but, this reflects emissions in 2014, not current emissions)
- **Public concern – many news articles and TV segments**
- Public meetings in La Place, LA
- Meetings with Louisiana Dept of Environmental Quality, State health officer, Parish president and council, school board, public safety, etc
- Political concern – letters to Administrator Pruitt from LA Senators and Congressmen
- Extensive engagement by many EPA organizations (ORD, R6, OAR, OEI, OGC, OECA)

Chloroprene: IRIS Assessment (2010)

- Conclusions:
  - **"Likely carcinogenic to humans" via mutagenic mode of action**
  - Cancer potency estimate = 1 in 10,000 risk at 0.2 ug/m^3
  - Inhalation Reference Concentration (RfC) = 20 ug/m^3
- EPA evaluated human epidemiological data, animal toxicology data, and evidence that chloroprene is mutagenic
  - In studies of occupational workers, there is evidence that chloroprene causes an increased risk of liver cancer, while other studies in humans show the possibility of increased lung cancer
  - In animal studies (including NTP), chloroprene has been shown to cause many different types of tumors, including tumors in the lung, circulatory system, liver, skin, and mammary gland, among others
  - Chloroprene's chemical structure is very similar to the known human carcinogens butadiene and vinyl chloride
- **Reviews of IRIS chloroprene assessment**
  - Extensive Agency, Interagency (NIEHS, OMB, CEQ, DOD, ATSDR) reviews
  - Independent external peer review panel unanimously concluded chloroprene is a likely human carcinogen that acts via a mutagenic mode of action

Denka Request for Correction

- Denka submitted Request for Correction of the IRIS assessment on June 26 2017
  - Challenged interpretation of epidemiological evidence
  - Challenged use of mouse National Toxicology Program study for IUR (cancer potency); interspecies differences, calculation methods
  - Disagree with cancer weight of evidence (WoE) classification
  - Point out that cancer potency is higher than for similar chemicals
  - Inhalation Reference Concentration should be reviewed
- EPA denied Request for Correction on January 25, 2018
  - Point-by-point basis for denial provided to Denka
    - Most points raised in RfC were considered during peer-review of 2010 IRIS Assessment
  - Systematic review of literature found no studies published since 2010 that would alter WOE or IUR
  - EPA identified issues with a 2012 physiologically-based pharmacokinetic (PBPK) model (Yang 2012) used to extrapolate study doses; issues are potentially resolvable for use in updating the IRIS assessment

Denka Actions: 2018

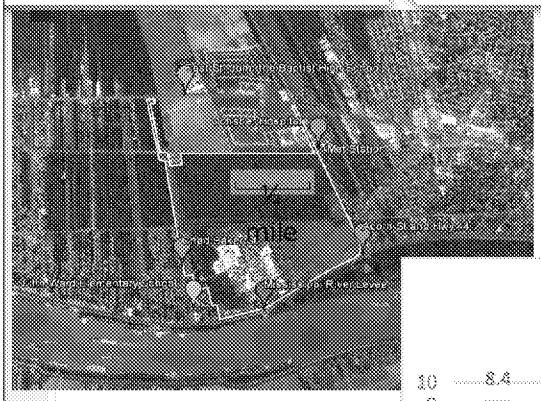
- Denka consultants (Ramboll) developing PBPK model
  - EPA provided quality assurance plan (QAPP) and written suggestions
  - EPA/Denka/Ramboll (with OAQPS and LA DEQ as observers) met July 2018 to discuss moving forward for PBPK model evaluation and peer review
  - Ramboll PBPK experts acknowledged limitations identified by EPA (e.g., model code not readily usable, need to better document empirical evidence that supports certain key assumptions used in model)
- Currently there are ongoing, collegial discussions amongst Ramboll and EPA PBPK experts to update the model to meet QAPP standards
  - EPA estimates ~1-4 months of additional work needed, contingent on Ramboll's ability to provide in vitro data that supports a key model assumption (waiting for Ramboll to provide existing data or generate new)
- Ramboll submitted Request for Reconsideration July 2018; EPA response due by end of November (options: deny, accept, or take more time)
- Denka installing emissions control measures

Deliberative Process / Ex. 5

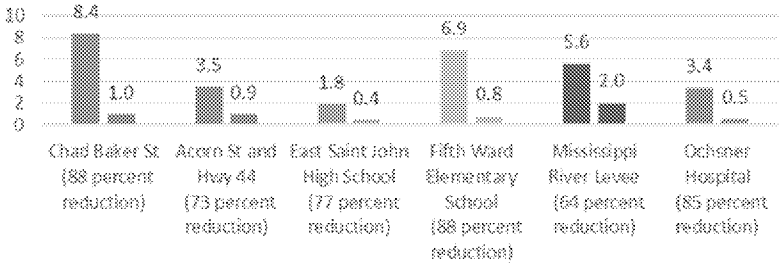
Denka Emissions Control

- Since Summer 2015, OAQPS, OECA, Region 6, and LDEQ have been actively working with Denka to monitor and reduce chloroprene emissions from the facility.
- In Jan 2017, Denka entered into an Administrative Order on Consent (AOC) with LDEQ to implement emission reduction measures.
- Emissions control measures put into place in early 2018; operational improvements continuing. Ambient air monitors are showing reductions in ambient concentrations at 6 locations surrounding the facility following control measure implementation.

Denka Emissions Control



Comparing pre-RTO and post-RTO average chloroprene concentrations (µg/m^3)



cumulative pre-RTO average 5/25/2016 - 2/27/2018 (211 sample days)
post-RTO average 3/02/2018 - 8/17/2018 (57 sample days)